Complete Summary

GUIDELINE TITLE

Prevention of rotavirus gastroenteritis among infants and children. Recommendations of the Advisory Committee on Immunization Practices (ACIP).

BIBLIOGRAPHIC SOURCE(S)

Parashar UD, Alexander JP, Glass RI, Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention. Prevention of rotavirus gastroenteritis among infants and children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2006 Aug 11;55(RR-12):1-13. [85 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Rotavirus gastroenteritis

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide recommendations on the use of rotavirus vaccine in infants and children

TARGET POPULATION

Infants from 6 to 36 weeks

INTERVENTIONS AND PRACTICES CONSIDERED

Immunization with live, oral, human-bovine reassortant rotavirus vaccine (RotaTeq®)

MAJOR OUTCOMES CONSIDERED

- Incidence of rotavirus gastroenteritis
- Adverse effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence

I. Evidence from randomized controlled trials
II. Evidence from other epidemiologic studies
III. Opinions of authorities

Strength of Evidence

A. Good evidence to support recommendation
B. Fair evidence to support recommendation
C. Insufficient evidence

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

In an analysis that used estimates of current rotavirus disease burden, vaccine efficacy, vaccine coverage rates, and health costs, investigators estimated that a national rotavirus vaccination program in which 3 doses of RotaTeq® are administered at ages 2, 4, and 6 months would result in 255,000 fewer physician visits, 137,000 fewer emergency department (ED) visits, 44,000 fewer hospitalizations, and 13 fewer deaths per year in children aged <5 years. From the health-care perspective alone, vaccination is likely to be cost-saving at a total cost per child (including administration costs) of up to $66 per child (approximately $12 per vaccine dose). A higher-priced vaccine would be increasingly unlikely to be cost-saving, and at a cost of more than $143 per child (approximately $38 per dose), a rotavirus vaccination program would most likely have a net cost to the health-care system. From the societal perspective, vaccination is likely to be cost-saving at a total cost per child of up to $156 per child (approximately $42 per dose). A higher-priced vaccine would be increasingly unlikely to be cost-saving, and at a cost of more than $268 per child (approximately $79 per dose), a rotavirus vaccination program would most likely have a net cost to society.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (I–III) and strength of evidence (A–C) supporting the recommendations are defined at the end of the "Major Recommendations" field.

Recommendations for the Use of Rotavirus Vaccine

Routine Administration

Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of U.S. infants with 3 doses of rotavirus vaccine administered orally at ages 2, 4, and 6 months (see Table below titled "Recommendations and quality of evidence for recommendations for use of rotavirus vaccine"). The first dose should be administered between ages 6–12 weeks. Subsequent doses should be administered at 4–10-week intervals, and all 3 doses of vaccine should be administered by age 32 weeks. Vaccination should not be initiated for infants aged >12 weeks because of insufficient data on safety of the first dose of rotavirus vaccine in older infants. Vaccine should not be administered after age 32 weeks because of insufficient data on the safety and efficacy of rotavirus vaccine in infants after this age. For infants in whom the first dose of rotavirus vaccine is inadvertently administered off label at age ≥13 weeks, the rest of the rotavirus vaccination series should be completed as per the schedule because timing of the first dose should not affect the safety and efficacy of the second and third dose. Infants who have had rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still initiate or complete the 3-dose schedule because the initial infection frequently provides only partial immunity.

Infants who are being breastfed can receive rotavirus vaccine. The efficacy of rotavirus vaccine is similar among breastfed and nonbreastfed infants. Like other vaccines, rotavirus vaccine can be administered to infants with transient, mild illnesses, and with or without low-grade fever.

Simultaneous Administration

Rotavirus vaccine can be administered together with diphtheria, tetanus, and pertussis vaccine (DTaP), Haemophilus influenzae type b conjugate (Hib) vaccine, inactivated poliovirus vaccine (IPV), hepatitis B vaccine, and pneumococcal conjugate vaccine. Available evidence suggests that the rotavirus vaccine does not interfere with the immune response to the Hib vaccine, IPV, hepatitis B vaccine, and pneumococcal conjugate vaccine, and the diphtheria and tetanus antigens in DTaP. Because validation of the pertussis assays is still under review,

insufficient immunogenicity data are available to confirm lack of interference of immune responses when rotavirus vaccine is concomitantly administered with childhood vaccines to prevent pertussis.

Contraindications

Rotavirus vaccine should not be administered to infants who have severe hypersensitivity to any component of the vaccine or who have experienced a serious allergic reaction to a previous dose of rotavirus vaccine.

Precautions

Altered Immunocompetence

Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence. Children and adults who are immunocompromised because of congenital immunodeficiency, hematopoietic transplantation, or solid organ transplantation sometimes experience severe, prolonged, and even fatal rotavirus gastroenteritis. However, no safety or efficacy data are available for the administration of rotavirus vaccine to infants who are potentially immunocompromised, including

- Infants with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system
- Infants on immunosuppressive therapy (including high-dose systemic corticosteroids)
- Infants with primary and acquired immunodeficiency states, including human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) or other clinical manifestations of infection with HIV; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. Data are insufficient from the clinical trials to support administration of rotavirus vaccine to infants with indeterminate HIV status who are born to mothers with HIV/AIDS.
- Infants who have received a blood transfusion or blood products, including immunoglobulins, within 42 days. In general, rotavirus vaccine should be deferred for 42 days following receipt of an antibody-containing product if possible. However, if the 42-day deferral would cause the first dose of rotavirus vaccine to be scheduled for age $\geq$13 weeks, a shorter deferral interval should be used to ensure the first dose is administered before age 13 weeks.

Acute Gastroenteritis

In usual circumstances, rotavirus vaccine should not be administered to infants with acute, moderate-to-severe gastroenteritis until the condition improves. However, infants with mild acute gastroenteritis can be vaccinated, particularly if the delay in vaccination might be substantial and might make the child ineligible to receive vaccine (e.g., aged $\geq$13 weeks before vaccination is initiated).

Rotavirus vaccine has not been studied among infants with concurrent acute gastroenteritis. In these infants, the immunogenicity and efficacy of rotavirus

vaccine can theoretically be compromised. For example, infants who receive oral poliovirus vaccine (OPV) during an episode of acute gastroenteritis in some instances have diminished poliovirus antibody responses to OPV.

Moderate-to-Severe Illness

Infants with moderate-to-severe illness should be vaccinated as soon as they have recovered from the acute phase of the illness. This precaution avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly attributing a manifestation of the underlying illness to the vaccine.

Preexisting Chronic Gastrointestinal Disease

Practitioners should consider the potential risks for and benefits of administering rotavirus vaccine to infants with preexisting chronic gastrointestinal disease. Infants with preexisting chronic gastrointestinal conditions who are not undergoing immunosuppressive therapy should benefit from rotavirus vaccine vaccination, and the benefits outweigh the theoretical risks. However, the safety and efficacy of rotavirus vaccine have not been established for infants with these preexisting conditions (e.g., congenital malabsorption syndromes, Hirschsprung's disease, short-gut syndrome, or persistent vomiting of unknown cause).

Intussusception

Following administration of a previously licensed rotavirus vaccine, RRV-TV, an increased risk for intussusception was observed. Available prelicensure data from a trial of 70,000 infants indicated no evidence of an association between intussusception and the current vaccine. However, additional postlicensure surveillance data are required to confirm that the vaccine is not associated with intussusception at a lower rate than would have been detected in prelicensure trials. In addition, data suggest that infants with a history of intussusception might be at higher risk for a repeat episode than other infants. Therefore, until postlicensure data on safety of rotavirus vaccine are available, the risks for and the benefits of vaccination should be considered when vaccinating infants with a previous episode of intussusception.

Special Situations

Premature Infants (<37 weeks' gestation)

Practitioners should consider the potential risks for and benefits of vaccinating premature infants against rotavirus. Limited data suggest that premature infants are at increased risk for hospitalization from viral gastroenteritis during their first year of life. In clinical trials, the safety and efficacy of rotavirus vaccine appears to be similar for premature and term infants, although a relatively small number of preterm infants have been evaluated. The lower level of maternal antibody to rotaviruses in very low birthweight, premature infants theoretically could increase the risk for adverse reactions from rotavirus vaccine. ACIP supports vaccination of prematurely born infants if they are at least aged 6 weeks, are being or have been discharged from the hospital nursery, and are clinically stable. Until further

data are available, ACIP considers that the benefits of rotavirus vaccine vaccination of premature infants outweigh the theoretical risks.

Exposure of Immunocompromised Persons to Vaccinated Infants

Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status can be vaccinated. The majority of experts believe the protection of the immunocompromised household member afforded by vaccination of young children in the household outweighs the small risk for transmitting vaccine virus to the immunocompromised household member and any subsequent theoretical risk for vaccine virus-associated disease. To minimize potential virus transmission, all members of the household should employ measures such as good hand washing after contact with the feces of the vaccinated infant (e.g., after changing a diaper).

Exposure of Pregnant Women to Vaccinated Infants

Infants living in households with pregnant women can be vaccinated. The majority of women of childbearing age would have pre-existing immunity to rotavirus and so the risk for infection and disease from potential exposure to the attenuated vaccine virus strain is low. In addition, no evidence exist that rotavirus infection or disease during pregnancy poses any risk to the fetus. Furthermore, vaccination of young children would avoid potential exposure of the pregnant women to wild virus if the unvaccinated infant suffers from rotavirus gastroenteritis.

Regurgitation of Vaccine

The practitioner should not readminister a dose of rotavirus vaccine to an infant who regurgitates, spits out, or vomits during or after administration of vaccine. The infant can receive the remaining recommended doses of rotavirus vaccine at appropriate intervals. Data are limited regarding the safety of administering a dose of rotavirus vaccine higher than the recommended dose and on the efficacy of administering a partial dose. Additional data on safety and efficacy are needed to evaluate the benefits of and risks for readministration.

Hospitalization After Vaccination

If a recently vaccinated child is hospitalized for any reason, no precautions other than routine universal precautions need be taken to prevent the spread of vaccine virus in the hospital setting.

Recommendations and Quality of Evidence for Recommendations for Use of Rotavirus Vaccine

	Level of Evidence	Strength of Evidence
Recommendations		
Routine vaccination at ages 2, 4, and 6 months	I	A
Administer to breastfed infants	I	A
Co-administer with DTaP, Hib vaccine, IPV, hepatitis B vaccine, and pneumococcal conjugate vaccine	I	A

Administer to infants with mild illness	I	B
Contraindications		
Serious allergy to a vaccine component or a previous vaccine dose	III	B
Precautions		
Altered immunocompetence	III	C
Moderate-to-severe illness, including acute gastroenteritis	III	C
Chronic gastrointestinal disease	III	C
History of intussusception	III	C
Special Situations		
Premature infants (aged <37 weeks)	I	B
Infants living in households with immunocompromised persons	III	C
Infants living in households with pregnant women	III	C
Regurgitation of vaccine	III	C
Children hospitalized after vaccination	III	C

Definitions:

Level of Evidence

I. Evidence from randomized controlled trials
II. Evidence from other epidemiologic studies
III. Opinions of authorities

Strength of Evidence

A. Good evidence to support recommendation
B. Fair evidence to support recommendation
C. Insufficient evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention of rotavirus gastroenteritis and associated morbidity and mortality among infants and children

POTENTIAL HARMS

A discussion of potential harms post-vaccination, including intussusception and other adverse events, can be found in the original guideline document.

CONTRAINDICATIONS

CONTRAINDICATIONS

Refer to "Major Recommendations" field for a description of contraindications to vaccine administration.

QUALIFYING STATEMENTS

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References to non-Centers for Disease Control (CDC) sites on the Internet are provided as a service to Morbidity and Mortality Weekly Report (MMWR) readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in MMWR were current as of the date of publication.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Parashar UD, Alexander JP, Glass RI, Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention. Prevention of rotavirus gastroenteritis among infants and children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2006 Aug 11;55(RR-12):1-13. [85 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug 11

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

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Advisory Committee on Immunization Practices

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site.

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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Date Modified: 10/2/2006